Complete Summary

GUIDELINE TITLE

Prostate cancer.

BIBLIOGRAPHIC SOURCE(S)

Prostate cancer. Philadelphia (PA): Intracorp; 2005. Various p. [23 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from April 1, 2005 to April 1, 2007.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Prostate cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Oncology
Radiation Oncology
Surgery
Urology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of prostate cancer that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

- Men with prostate cancer
- Asymptomatic men at high risk of prostate cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests:
    - Blood tests
        - Prostate-specific antigen (PSA)
        - Percent free PSA (%fPSA), free-to-total PSA ratio (fPSA/tPSA) testing, and complexed PSA (cPSA) testing
    - Digital rectal examination (DRE)
    - Transrectal ultrasound (TRUS)
    - Biopsy
    - Computerized tomography (CT) of abdomen, pelvis, bone
    - Magnetic resonance imaging (MRI) if indicated
    - Renal function test (RFT) or intravenous pyelogram (IVP)
    - Genetic testing

Management/Treatment

1. Watchful waiting
2. Prostatectomy

3. Radiation therapy including external beam radiation and brachytherapy
4. Prostatectomy and bilateral orchiectomy
5. Androgen suppression (luteinizing hormone-releasing hormone [LHRH] agonists) with or without androgens
6. Systemic chemotherapy
7. Other agents (bisphosphonates, signal transductal-modulating agents, immunotherapy, and gene therapy) (under investigation)
8. Physical therapy if indicated
9. Referral to specialists
10. Case management strategies, including case initiation, case management focus, and discharge

MAJOR OUTCOMES CONSIDERED

- Risk factors for prostate cancer
- Sensitivity and accuracy of diagnostic tests
- Effectiveness of treatment
    - Survival
    - Prostate specific antigen (PSA) levels

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Difficulty voiding or urinary retention
- Increased urinary frequency
- Blood in urine
- Back pain
- In many instances, there are no overt symptoms.

Objective Findings

- Hard nodular prostate on physical exam
- Hematuria
    - Presence of red blood cells on urinalysis
    - Frank blood in urine
- Scrotal edema; indicative of extensive disease
- Signs of spinal cord compression; indicative of widespread metastatic disease

Diagnostic Tests

Blood tests that may be ordered

- Prostate-specific antigen (PSA), serum tumor marker
    - Normal value: <40 yr old 0.0 to 2.0 ng/mL; >40 yr old 0.0 to 4.0 ng/mL
        - PSA is the principal screening test for prostate cancer and is most useful when combined with digital rectal exam (DRE) and transrectal ultrasound (TRUS).

Recommend screening prostate-specific antigen (PSA) testing when ANY of the following medical necessity criteria are met:

- For asymptomatic men at any age who are at high risk of prostate cancer due to ANY of the following:
    - Family history (e.g., multiple first-degree relatives diagnosed at an early age)
    - African-American race
    - Previous borderline PSA levels
    - For asymptomatic men who are aged 50 to 75 years with a life expectancy of at least 10 years

Recommend percent free PSA (%fPSA) or free-to-total PSA ratio (fPSA/tPSA) testing and complexed PSA (cPSA) testing when the following medical necessity criterion is met:

- For clinical decision-making regarding the need for prostate biopsy in men with a normal or equivocal digital rectal examination (DRE) and elevated tPSA of 4 to 10 ng/mL

Diagnostic Tests

- Transrectal ultrasound (TRUS)
    - TRUS is a principal screening test used in combination with DRE and PSA. It has a 57 to 68% sensitivity or ability to detect prostate cancer in asymptomatic men
    - American Cancer Society (ACS) recommends obtaining TRUS for more detailed diagnosis if the DRE performed by a skilled health care professional reveals an abnormal finding.
- Biopsy
    - Definitive diagnostic biopsy is indicated in men over age 40 with elevated PSA, abnormal digital rectal examination (DRE), abnormal ultrasound of the prostate (TRUS), and urinary symptoms without an obstructive etiology of symptoms.
- Computerized tomography (CT) of abdomen, pelvis, bone (see the Intracorp Imaging guidelines)
    - CT scans are not considered sufficient to determine presence or extent of disease and metastasis
- Magnetic resonance imaging (MRI) (see the Intracorp Imaging guidelines.)
    - MRI scans are considered controversial and should be performed only if CT scans are inconclusive.
- Renal function tests (RFT) or Intravenous pyelogram (IVP)
    - RFT or IVP may be performed to detect kidney damage, especially after longstanding urethral obstruction and/or urinary retention.
- Genetic testing
    - When the newly discovered gene HPC-1 is present, a patient is believed to have an enhanced potential to develop prostate cancer; nevertheless, genetic testing is controversial.

Differential Diagnosis

- Benign prostatic hyperplasia (see the Intracorp guideline Prostatism [BPH])
- Prostatitis
- Local infection
- Prostatic calculi
- Prostate intraepithelial neoplasia (PIN); a prostate cancer precursor lesion

<u>Treatment Options</u>

- Localized disease:
    - Watchful waiting
    - Anatomic radical retropubic prostatectomy
    - External beam radiation
    - Brachytherapy (or interstitial therapy): the implantation of radioactive "seeds" directly into or near a cancerous tumor
    - Adjuvant androgen suppression can improve survival for some men treated with external beam radiation.

        - Progressive rise in serum PSA after treatment is indicative of cancer recurrence.
        - Radiation therapy can be effective to treat local cancer recurrences after prostatectomy.
        - Depending upon treatment regimen, associated side effects of treatment for localized prostate cancer include:
            - Erectile dysfunction
            - Irritative voiding symptoms
            - Difficulty with urinary control
            - Rectal irritation
- Advanced disease:
    - Prostatectomy, bilateral orchiectomy
    - Androgen suppression; most often using luteinizing hormone-releasing hormone (LHRH) agonists, with or without antiandrogens
        - Side effects of LHRH protocol include decreased libido, hot flashes, gynecomastia, loss of lean muscle mass and bone density
    - Progressive androgen independent cancers can be treated with systemic chemotherapy; clinical trials are currently underway to assess impact of chemotherapy on prostate cancer survival
- Other agents (bisphosphonates, signal transduction-modulating agents, immunotherapy, and gene therapies) are also under evaluation in clinical trials. Recent studies suggest that intermediate- and high-risk patients treated with radical prostatectomy or external beam radiation score better on 5-year PSA outcomes than patients treated by implant radiation. Outcomes in low-risk patients are not significantly influenced by the treatment type.
    - Care Setting: acute inpatient. (Pre-operative laboratory tests and hydration rarely require inpatient admission)
- Radiation therapy, including external beam and brachytherapy (implanted or seeded radiation)
    - Radiation Care Setting: clinic or free-standing outpatient, or physician's office
- Neoadjuvant hormonal therapy: because PSA expression itself is under hormonal control, androgen deprivation therapy can decrease the serum level of PSA independent of tumor response; clinicians cannot rely solely on the serum PSA level to monitor a patient's response to hormone therapy but must also follow clinical criteria
    - Care Setting: self-administered

Duration of Medical Treatment

- Medical - Optimal: 90 day(s), Maximal: 365 day(s)

Additional information regarding primary care visit schedules, referral options, specialty care, and physical therapy is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Resolving urinary symptoms, urinary tract infection, or obstruction
- After radiation or hormonal therapy

- After hospitalization for surgery (prostatectomy)

Note: Some patients with this condition may never return to work

Case Management Directives (refer to the original guideline for detailed recommendations)

Case Initiation

Establish Case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- See Chemotherapy Chart in the original guideline document.
- The American Joint Committee on Cancer encourages use of the "TNM" classification system (T=primary tumor size; N=lymph node involvement; M=metastasis).
- Provide contact information for local and national support groups.

Coordinate Care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity Deficit

- Instruct regarding post-prostatectomy avoiding strenuous exercise, lifting, sitting for long intervals, straining, plus sexual activities. (See the Intracorp guideline Prostatectomy).
- Encourage perineal exercise of squeezing buttocks 1 to 10 times per hour within 24 to 48 hours after surgery.
- Document activity alteration as none, mild, moderate, severe, dependent, or bed-bound (based on most recent performance status) and interventions required.

Chemotherapy Intolerance

- Assess status, acute versus chronic, of toxic side effects on rapidly growing tissues, including bone marrow, epithelium, hair, sperm, and document intervention recommended.

Hemodynamic Instability

- Document bleeding complications, severity, and intervention recommended.

Immune Compromised

- Document establishment of protective isolation measures for a white blood cells count (WBC) less than 1,000/mm^3, implying dangerous susceptibly to infection.

Inadequate Nutrition

- Assess presence and severity of constipation after prostatectomy.
- Assess for insufficient urinary elimination by abdominal or suprapubic distention and decreased urine or urine stream caliber or force.
- Use optimal goal of remaining within 10% of pretreatment weight to document hydration and nutrition deficit as mild, moderate, severe and response needed.

Mental and Emotional Alteration

- Ensure accurate diagnosis of any change in mental status.
- Document baseline or optimal mental and emotional functioning and their alterations due to cancer presence, comorbidity, surgery, or treatments.
- Assess and respond appropriately to the degree of debility caused by alterations listed in the original guideline through benefit coordination or community resource activation.

Pain Control

- Evaluate pain due to bladder distention and spasms (prostatectomy) or due to drains and large dressings (perineal prostatectomy) and nursing interventions done.
- Document optimal pain management by characterizing severity and interventions undertaken to remedy or manage pain.

Oncologic Emergencies

- Contact physician or surgeon immediately or activate emergency medical technician (EMT) system for signs of abdominal distention, bladder spasms, cystitis or proctitis (especially following radiation therapy), frank bleeding or blood in urine, infection, pain or burning during urination, thrombophlebitis (especially associated with diethylstilbestrol [DES] hormonal therapy), urethral stricture.
- Document presence of or developing oncologic emergencies and report to attending physician, surgeon, or activate EMT system as necessary.

Radiation Intolerance

- Document presence and severity of radiation side effects.
- Initiate early interventions for complications of radiation therapy.

Respiratory Instability

- Document respiratory deficit as mild, moderate, severe, and dependent, and respiratory rehabilitation enhancement measures.

Skin Integrity Deficit

- Document severity of skin integrity disruption.

Terminal Care

- Document optimal comfort measures and palliative care initiatives.

Discharge

Discharge from Case Management (CM)

- Document return to independence or stabilized functional status and closing conversations with patient, caregiver, physician, pharmacist, and care providers.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefits

Appropriate diagnosis, treatment, and management of prostate cancer that assist medical management leaders to make appropriate benefit coverage determinations

Specific Benefits

- Transrectal ultrasound (TRUS) has a 57 to 68% sensitivity, or ability to detect prostate cancer in asymptomatic men.
- Adjuvant androgen suppression can improve survival for some men with localized disease who are treated with external beam radiation.
- Radiation therapy can be effective to treat local cancer recurrences after prostatectomy
- Recent studies suggest that intermediate-and high-risk patients treated with radical prostatectomy or external beam radiation score better on 5-year prostate specific antigen (PSA) outcomes than patients treated by implant radiation.

POTENTIAL HARMS

- Refer to the Case Management Focus section of the "Major Recommendations" field for information on potential complications and strategies to address them, or refer to the original guideline document.
- Depending upon treatment regimen, associated side effects of treatment for localized prostate cancer include erectile dysfunction, irritative voiding symptoms, difficulty with urinary control, rectal irritation.
- Side effects of luteinizing hormone-releasing hormone (LHRH) protocol include decreased libido, hot flashes, gynecomastia, loss of lean muscle mass and bone density.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Prostate cancer. Philadelphia (PA): Intracorp; 2005. Various p. [23 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2005)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

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Reprints of complete guideline content may be purchased for $35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 25, 2005. The information was verified by the guideline developer on June 7, 2005.

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